

DEPARTMENT OF WEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Carprofen

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

DMB

Display Date	<u>12-4-01</u>
Publication Date	<u>12-5-01</u>
Certifier	<u>S. Reine</u>

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for a once daily, 2-milligram per pound (mg/lb) dosage of carprofen, by oral caplet, for the relief of pain and inflammation associated with osteoarthritis in dogs.

DATES: 'This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed a supplement to approved NADA 141-053 that provides for veterinary prescription use of RIMADYL (carprofen) Caplets for the relief of pain and inflammation associated with osteoarthritis in dogs. The supplemental NADA provides for a once daily, 2-mg/lb dosage for the oral caplet dosage form. The supplemental application is approved as of September 27, 2001, and the regulations are amended in 21 CFR 520.309 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11 (e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for non-food-producing animals qualifies for 3 years of marketing exclusivity beginning September 27, 2001, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

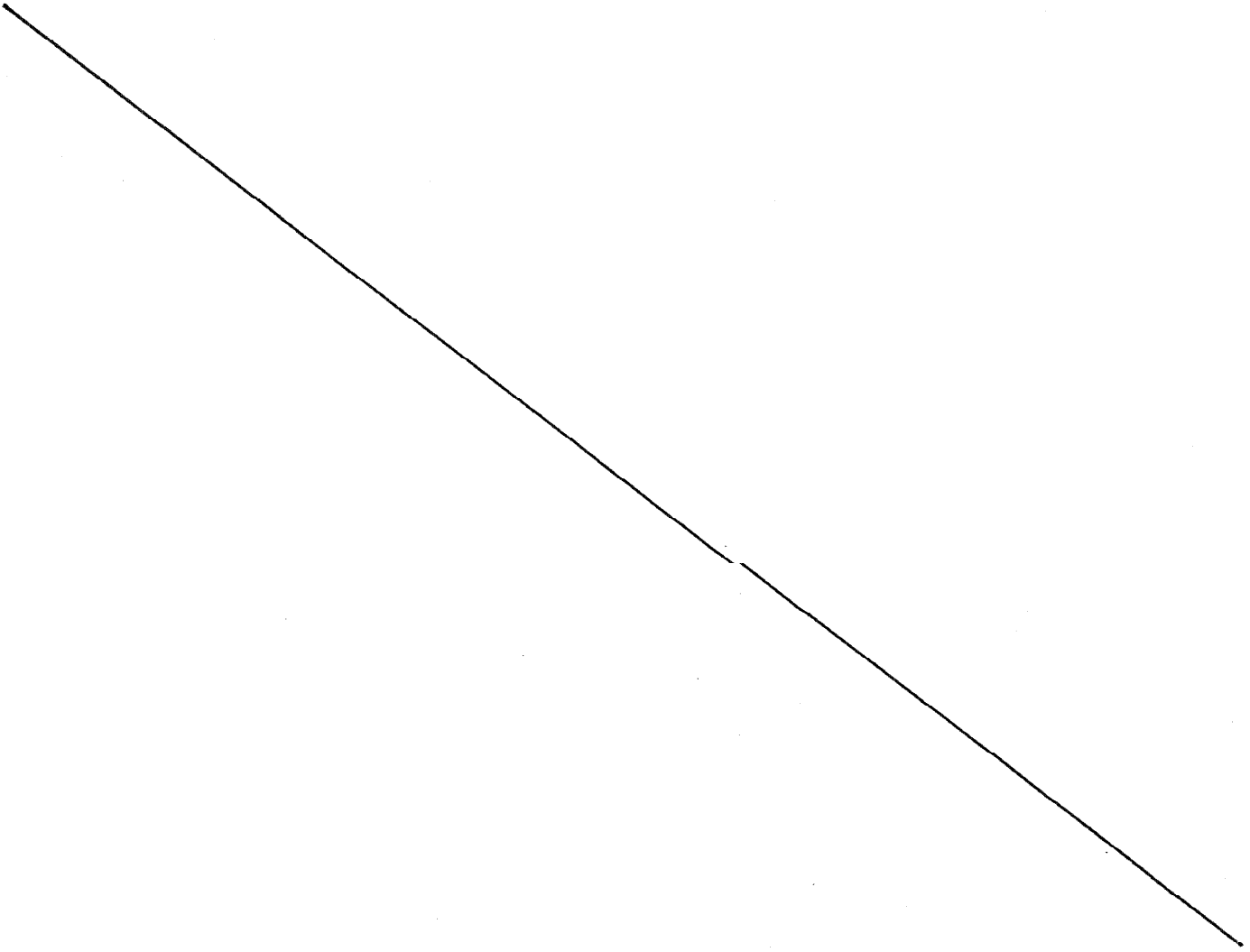
2. Section 520.309 is amended in paragraph (a) by adding “(mg)” after “milligrams”; and by revising paragraph (d) to read as follows:

§ 520.309 Carprofen.

* * * * *

(d) *Conditions of use* in dogs--(l) *Amount*—(i) *Caplet*. 2 mg per pound (lb) of body weight once daily or 1 mg/lb twice daily.

(ii) *Chewable tablet*. 1 mg/lb twice daily.



(2) *Indications for* use. For the relief of pain and inflammation associated with osteoarthritis in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 11/9/01
November 9, 2001.

87 S/A
Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

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